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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/014,485  | 11/13/2001  | Michael J. Comb      | CST-138 CIP2        | 4101             |
| 31012   | 7590        | 06/08/2004           | EXAMINER            |                  |
| JAMES GREGORY CULLEM, ESQ.<br>INTELLECTUAL PROPERTY COUNSEL<br>CELL SIGNALING TECHNOLOGY, INC.<br>166B CUMMINGS CENTER<br>BEVERLY, MA 01915 |             |                      | CANELLA, KAREN A    |                  |
|   |             | ART UNIT             | PAPER NUMBER        |                  |
|   |             | 1642                 |                     |                  |
| DATE MAILED: 06/08/2004   |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |              |
|------------------------------|-----------------|--------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s) |
|                              | 10/014,485      | COMB ET AL.  |
|                              | Examiner        | Art Unit     |
|                              | Karen A Canella | 1642         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_.
- 2a)  This action is **FINAL**.                            2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 1-4 and 11-45 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) 1-4 and 11-45 are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Please note that the examiner assigned to this application has changed.
2. Claims 5-10 have been canceled. Claims 2-4, 11-13, 15, 16, 21 and 23-25 have been amended. Claims 1-4 and 11-45 are pending. Upon review and reconsideration, the restriction and species election requirement of the Paper mailed September 17, 2003 is withdrawn. Claims 1, 17-20, 22 and 27-45, listed as withdrawn based on the former Restriction Requirement, will be re-joined for the following Restriction Requirement.

#### ***Election/Restrictions***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-4, 11, 12, 14-24, 26, and 37-43, drawn to a method of producing a motif-specific, context independent antibody that recognizes a plurality of peptides within a genome that contain the motif, wherein the motif is a kinase consensus substrate motif selected from the group consisting of a MAPK, CDK, PKA, Akt, PKC and ATM consensus substrate motif, and antibodies made thereby, classified in class 436, subclass 547, class 424, subclasses 130.1 and 185.1, and class 530, subclass 389.1. Claims 1-4, 11, 12, 14-24, 26, 37-43 will be examined to the extent that they read on antibodies which bind the kinase consensus substrate motif selected from the group consisting of a MAPK, CDK, PKA, Akt, PKC and ATM consensus motifs.
  - II. Claims 1-4, 11, 13, 14-23, 25, 26, 37-41 and 45, drawn to a method of producing a motif-specific, context independent antibody that recognizes a plurality of peptides within a genome that contain the motif, wherein the motif is a kinase consensus substrate motif selected from the group consisting of a PKC Zeta, ABL, CDK5, CAMKII, Src kinase, CDC2/CDK2 s, and a GSK3 kinase consensus substrate motif, and antibodies made thereby, classified in class 436, subclass 547, class 424, subclasses 130.1 and 185.1, and class 530, subclass 389.1. Claims 1-4, 11, 13, 14-23, 25, 26, 37-41 and 45 will be examined with this group to the extent that they read on antibodies which bind to PKC Zeta, ABL, CDK5,

CAMKII, Src kinase, CDC2/CDK2 s, and GSK3 kinase consensus substrate motifs.

- III. Claims 1–4, 11-26, 37-43, and 45 drawn to a methods of producing a motif-specific, context independent antibody that recognizes a plurality of peptides within a genome that contain the motif, wherein the motif is a protein binding motif selected from the group consisting of a 14-3-3 consensus binding motif, a PDK1/bulky-ring consensus docking motif and a P13K P85 consensus binding motif and antibodies made thereby, classified in class 436, subclass 547, class 424, subclasses 130.1 and 185.1, and class 530, subclass 389.1. Claims 1-4, 11-26, 37-43, and 45 will be examined with this group to the extent that they read on antibodies which bind to PDK1/bulky-ring consensus docking motif and a P13K P85 consensus binding motif.
- IV. Claims 27-35, drawn to in vitro methods of screening and detecting proteins which bind to a motif-specific, context independent antibody that recognizes a plurality of peptides within a genome that contain the motif, wherein the motif is a kinase consensus substrate motif selected from the group consisting of a MAPK, CDK, PKA, Akt, PKC and ATM consensus substrate motif, classified in class 435, subclasses 7.1 and 973. Claims 27-35 will be examined with this group to the extent that they read on antibodies which bind the kinase consensus substrate motif selected from the group consisting of a MAPK, CDK, PKA, Akt, PKC and ATM consensus motifs
- V. Claims 27-34 and 36, drawn to in vitro methods of screening and detecting proteins which bind to a motif-specific, context independent antibody that recognizes a plurality of peptides within a genome that contain the motif, wherein the motif is a kinase consensus substrate motif selected from the group consisting of a PKC Zeta, ABL, CDK5, CAMKII, Src kinase, CDC2/CDK2 s, and a GSK3 kinase consensus substrate motif, classified in class 435, subclasses 7.1 and 973. Claims 27-34 and 36 will be examined with this group to the extent that they read on antibodies which bind to PKC Zeta, ABL, CDK5, CAMKII, Src kinase, CDC2/CDK2 s, and a GSK3 kinase consensus substrate motifs.

VI. Claims 27-36, drawn to in vitro methods of screening and detecting proteins which bind to a motif-specific, context independent antibody that recognizes a plurality of peptides within a genome that contain the motif, wherein the motif is a protein binding motif selected from the group consisting of a 14-3-3 consensus binding motif, a PDK1/bulky-ring consensus docking motif and a P13K P85 consensus binding motif, classified in class 435, subclasses 7.1 and 973. Claims 27-36 will be examined with this group to the extent that they read on antibodies which bind to a 14-3-3 consensus binding motif, a PDK1/bulky-ring consensus docking motif and a P13K P85 consensus binding motif.

4. The inventions are distinct, each from the other because of the following reasons:

The antibodies of Groups I, II and III are structurally and functionally different products which are made by the different claimed methods and have different uses. The examination of all antibodies would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups I, II and III differ from the methods of Groups IV, V and VI in method objectives, method steps and parameters and in the reagents used.

The antibodies of inventions I, II and III are related to the methods of Inventions IV, V and VI, respectively, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ' 806.05(h)). In the instant case the antibodies of Groups I, II and III can each be used in a method to raise an anti-idiotypic antiserum or anti-idiotypic monoclonal antibody.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

5. In the event applicant elects Groups I or IV:

This application contains claims directed to the following patentably distinct species of the claimed invention, antibodies binding to the consensus binding motifs of MAPK, CDK, PKA, Akt, PKC and ATM.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 11, 12, 14-24, 26, 27-35 and 37-43 generic.

6. In the event applicant elects Groups II or V:

This application contains claims directed to the following patentably distinct species of the claimed invention: antibodies binding to the consensus binding motifs of PKC Zeta, ABL, CDK5, CAMKII, Src kinase, CDC2/CDK2 s, and a GSK3.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 11, 13, 14-23, 25, 26, 27-34, 36, 37-41, 45 are generic.

7. In the event applicant elects Groups III or VI:

This application contains claims directed to the following patentably distinct species of the claimed invention: antibodies binding to the protein binding motifs of 14-3-3 consensus binding motif, PDK1/bulky-ring consensus docking motif and P13K P85 consensus binding motif

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 11-26, 27-36, 37-43, 45 are generic.

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.  
06/07/2004

*Karen A. Canella*  
KAREN A. CANELLA PH.D  
PRIMARY EXAMINER